REMARKS

Claims 1, 3-6, 12, and 13 are pending in the present application. Entry of the Reply after Final under 37 C.F.R. § 1.116 filed on June 25, 2004 into the record of the present application is requested in the Request for Continued Examination (RCE) filed concurrently herewith. Applicants also request entry of the instant Supplemental Reply, which responds to assertions made by the Examiner in the Advisory Action issued on July 9, 2004.

The Advisory Action indicates that claims 1, 3-6, 12, and 13 remain rejected. In the Advisory Action, the Examiner asserts that the Reply After Final raises "new issues" and issues of "new matter" in that the claim limitations "are not supported by the specification." Applicants respectfully traverse the Examiner's comments with regard to the issues of new matter as stated in the Advisory Action. Specifically, Applicants respectfully point out that all of the features recited in the pending claims are indeed supported by the specification.

In the Reply after Final, claim 1 was amended as follows:

Claim 1. A method for inhibiting the degradation of ~~activation of a substance degrading~~ brain natriuretic peptide in a specimen, which comprises

~~placing~~ collecting the specimen containing brain natriuretic peptide into a container, wherein the face coming into contact with

the specimen is made of or coated with a material selected from the group consisting of silicone and plastics, and

excluding the addition of any inhibiting agents,

by which the ratio of residual BNP immunoreactivity is 50% or more after 24 hours standing at 25°C.

Similar amendments were made to claims 6, 12, and 13. The recitation of "A method for inhibiting the degradation of brain natriuretic peptide in a specimen" is supported in the present specification at page 9, lines 6-7, wherein it is stated, "The residual activity of BNP remarkably decreased in glass tubes because BNP was degraded by substances degrading the peptides such as proteases." Further support is found on page 9, lines 15-16, which states, "The method of this invention for inhibiting the peptide degradation…."

Support for "collecting the specimen containing brain natriuretic peptide into a container…" is found in the specification, such as on page 7, lines 15-19, which states, "Fifty ml of venous blood from normal subject was collected into a blood-collecting tubes containing EDTA (1.5 mg/ml EDTA·2Na). Human α-BNP (Peptide Institute) was added to the collected blood to make its final concentration 200 pg/ml, to prepare a specimen."

As noted in the Reply after Final filed on June 5, 2003, support for the phrase "excluding the addition of any inhibiting

agents" is found in the specification as follows.

- On page 2, lines 3-6, the specification discloses that, in order to correctly measure the concentration of natriuretic peptides, prior methods required the addition of degradation-inhibiting agents, such as aprotinin. The specification states that these methods are disadvantageous because they were complicated and required too many steps to perform.
- Page 3, lines 2-9, the specification discloses that the present invention eliminates the complicated handling of specimens described above by using the containers described.
- Page 4, lines 18-19, the specification states, "This invention relates to a measurement of natriuretic peptide in specimens which do not contain aprotinin." Thus, the specification literally states that the specimen does not contain this degradation-inhibiting agent.

- Examples 1-3, pages 6-8, the specification discloses experiments for the measurement of brain natriuretic peptide (BNP). In Example 1, BNP is measured in glass tubes, in Example 2, BNP is measured in polyethylene terephthalate (PET) tubes, and in Example 3, BNP is measured in plastic tubes. In all of these Examples, BNP is measured in containers in the absence of any degradation-inhibiting agents.

Finally, the addition of "the ratio of residual BNP immunoreactivity is 50% or more after 24 hours standing at 25°C" is supported in the specification at page 8, lines 24 and 26, which states "The ratios of the residual BNP activities were 50% or more due to the suppression of the activity of substances degrading peptides by using any kinds of plastic tube used..." and page 8, line 21, which states, "They were allowed to stand for 0, and 24 hours at room temperature (25 °C)." Further support is found on page 6, lines 20-27, which describes the method of measuring BNP immunoreactivities. The same method was utilized in Example 3.

Based on the above, Applicants respectfully submit that all claim limitations are fully supported by the specification.

Conclusion

Applicants respectfully submit that the pending claims define patentable subject matter such that this application should be placed into condition for allowance. Early and favorable action on the merits of the present application is thereby requested.

If there are any minor matters precluding allowance of the present application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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